

## **DETAILED ACTION**

### ***Status of the Application***

1. Claims 1-38 have been examined in this application. This is a Final Office Action in response to the “Amendment” and “Remarks” filed on December 22, 2009.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-2, 4-7, 9-14, 15-20, 22, 24-27, 29-32, 34, 36-38 rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Number 5,832,449 to Cunningham in view of US Patent Number 5,945,651 to Chorosinski and in even further view of US Patent Number 5,098,131 to Tucker.

(A) As per claim 1, Cunningham teaches a computer implemented method for tracking distribution of pharmaceutical drug samples prescribed by a prescriber to a prescribed patient (Cunningham: Col. 11, Ln. 53-Col. 12, Ln. 11),

comprising a step of adjudicating, at a health plan adjudication database system, a claim associated with the prescribed patient by a drug dispenser for the use of a token representative of a pharmaceutical drug sample (Cunningham: Figure 1—Item 12--Col. 10, Ln. 39-Col. 11, Ln. 40) (Note: In Cunningham, item 12 in Figure 1 represents a central computing station through which a pharmacy or drug dispenser attempts to adjudicate or validate the token or product trial media and the Office takes the position that it is within the scope of Cunningham that this central

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computer, represented by numeral 12, is part of a health plan adjudication database system because as Figure 1 illustrates, the central computing system is separate from the computer system of the drug dispensers (pharmacies) or the prescribers. Even assuming that the central computing station denoted by numeral 12 belongs to a pharmaceutical manufacturer, the central computing station can still be considered to be part of a health plan adjudication database system because the pharmaceutical manufacturer which is administering the sample drug distribution program can be considered to be administering a health plan (the "health plan" comprising the drug sample distribution program) and adjudicating or approving the use of the tokens or product trial media prior to the dispensing of the pharmaceutical product sample.);

the token having been distributed by a drug dispenser to the prescriber (Cunningham: Figure 4A and Col. 7, Ln. 50-67)

the token is provided by the prescriber to the patient for obtaining the pharmaceutical drug sample from the drug dispenser (Cunningham: Col. 5, Ln. 40-45 and Col. 10, Ln. 21-26 and 39-50).

In Cunningham, the patient is not pre-identified, however, the Office takes the position that this feature is well known in the health care and pharmaceutical dispensing industry (i.e. to identify a patient on a prescription or a token to redeem to pharmaceutical sample) as is illustrated by Chorosinski (Col. 7, Ln. 24-46). At the time of the invention, it would have been obvious for one of ordinary skill in the prescription dispensing industry to have modified the teachings of Cunningham with this aforementioned teachings from Chorosinski with the motivation of having a means of identifying a patient who redeems a pharmaceutical prescription or pharmaceutical sample, as recited in Chorosinski (Col. 5, Ln. 24-46). One of ordinary skill in

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the art in the pharmaceutical dispensing industry would make this modification to Cunningham to ensure that prescription fraud does not take place and also to ensure that the prescription sample or prescription is dispensed only to the correct, identified patient since prescriptions or prescription samples can be dangerous if taken without authorization or approval for an authorized prescriber.

The combined teachings of Cunningham in view of Chorosinski do not teach or suggest the following features which are taught by Tucker (Col. 3, Ln. 28-42):

wherein the token (coupon) displays token processing information, the token processing information at least including contact information for adjudication assistance.

(Note: Tucker does not state that the information included on the token (coupon) for the retailer is contact information for adjudication assistance, however, the Office takes the position that this feature is inherent from the disclosure of Tucker because once a consumer has purchased a product or a service using a token (coupon) and has given the token (coupon) to the retailer then the retailer has no other use for the token (coupon) other than to seek reimbursement for the consumer's use of the token (coupon) from the issuer of the token (coupon) and the retailer's seeking reimbursement for the consumer's use of the token (coupon) from the issuer of the token (coupon) necessarily involves that the retailer be given contact information so that they can at least begin the process of reimbursement (adjudication) for allowing the consumer to use the token (coupon).)

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the combined teachings of Cunningham in view of Chorosinski with these aforementioned teachings from Tucker with the motivation of having a means of providing the

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retailer with instructions so that they could ultimately and properly dispose of the token (coupon).

(B) As per claim 2, in Cunningham in view of Chorosinski, in view of Tucker the step of adjudicating comprises steps of: receiving at the claim adjudication system a request for adjudication in a first predefined format from the drug dispenser; and sending to the drug dispenser an adjudication response in the predefined format in response to the request for adjudication (Cunningham: Figures 7A-7B and Col. 10, Ln. 39-50). (The Office takes the position that the procedure or algorithm set forth in the above quoted section of Cunningham and in the above quoted figures of Cunningham set forth a predefined format of sending a request for adjudication from the drug dispenser to the health plan adjudication database system and for sending to the drug dispenser an adjudication response in the predefined format in response to the request for adjudication.).

(C) As per claim 4, Cunningham in view of Chorosinski in view of Tucker teaches that the steps of receiving and sending are performed using a communications network for communications between a plurality of drug dispensers and a plurality of adjudicators for the electronic processing of pharmacy claims (Cunningham: Figure 1 and Col. 4, Ln. 65-Col. 5, Ln. 45).

(D) As per claim 5, in Cunningham in view of Chorosinski in view of Tucker the step of adjudicating further comprises the steps of: receiving information about tokens that are distributed; receiving information about the token from the drug dispenser; and processing the request to provide the adjudication response using the information about tokens that were

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distributed, the information about the tokens from the drug dispenser, and business logic related to the token (Cunningham: Col. 10, Ln. 21-50; Col. 11, Ln. 40-Col. 12, Ln. 11).

(E) As per claim 6, Cunningham in view of Chorosinski in view of Tucker teaches that the step of adjudicating further comprises a step of receiving information about the prescribers to which tokens were distributed, wherein the information about the token received from the drug dispenser comprises prescriber information, and the step of processing further comprises a step of comparing the information about the prescriber with the information about the prescribers to which tokens are distributed (Cunningham: Col. 11, Ln. 53-Col. 12, Ln. 25).

(F) As per claim 7, Cunningham in view of Chorosinski in view of Tucker teaches that the step of adjudicating further comprises steps of storing token usage data related to the token, and periodically providing the token usage data to enable evaluation of a pharmaceutical drug sample distribution program (Cunningham: Col. 11, Ln. 40-Col. 12, Ln. 25).

(G) As per claim 9, Cunningham in view of Chorosinski in view of Tucker teaches a step of entering information related to the token into a pharmacy benefit management system used for dispensing pharmaceutical drugs and for sending and receiving adjudication communications (Cunningham: Col. 11, Ln. 30-Col. 12, Ln. 25).

(H) As per claim 10, Cunningham in view of Chorosinski in view of Tucker further comprises a step of distributing token for delivery to prescribers (Cunningham: Col. 4, Ln. 65-Col. 5, Ln. 62 and Col. 9, Ln. 13-16).

(I) As per claim 11, Cunningham in view of Chorosinski in view of Tucker further comprises a step of storing token distribution data related to the tokens, the token distribution

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data including prescriber information to identify prescribers to whom the tokens were distributed (Cunningham: Col. 11, Ln. 40-52).

(J) As per claim 12, Cunningham in view of Chorosinski in view of Tucker further comprises the steps of periodically receiving token usage data related to the token, the token usage data being generated and stored by the claim adjudication system, and correlating the token usage data with token distribution data (Cunningham: Col. 9, Ln. 13-16 and Col. 11, Ln. 30-Col. 12, Ln. 17).

(K) As per claim 13, Cunningham in view of Chorosinski in view of Tucker further comprises a step of prescribing the pharmaceutical drug sample for a patient using the token (Cunningham: Col. 10, Ln. 22-27).

(L) As per claim 14, Cunningham in view of Chorosinski in view of Tucker further comprises a step of accounting to the drug dispenser for the dispensing of the pharmaceutical drug sample (Cunningham: Col. 12, Ln. 4-11).

(M) As per claims 15-20, 22, 24-27, 29-32, 34 and 36-38 these claims are substantially similar to Claims 1-2, 4-7 and 9-14, and are therefore rejected on the same basis as these claims, which is set forth above.

4. Claims 3, 23, 28 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable Cunningham in view of Chorosinski in view of Tucker as applied to Claim 2, 22, 27, 34, above, respectively, and in further view of US Patent Number 5,666,490 to Gillings.

(A) As per claim 3, Cunningham does not teach that the step of receiving and sending are performed in accordance with a protocol for electronic processing of pharmacy benefit claims, however, this feature is well known in the art as evidenced by Gillings (Claim 1, part (k)). At the

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time of the invention, it would have been obvious for one of ordinary skill in the art to have modified Cunningham in view of Chorosinski in view of Tucker with the aforementioned feature from Gillings with the motivation of improving the quality and integrity of the process of managing pharmaceutical data, as recited in Gillings (Col. 1, Ln. 65-Col. 2, Ln. 3).

(B) As per claims 23, 28 and 35, these claims repeat features previously addressed in the rejection of claims 1-14 and are rejected on the same basis.

5. Claim 8, 21 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham in view of Chorosinski in view of Tucker, as applied to Claim 1, 15, 27, above, respectively, and in further view of US Patent Number 6,564,121 to Wallace.

(A) As per claim 8, Cunningham does not teach or suggest that the step of adjudicating further comprises a step of providing one or both formulary management services and drug utilization review services, however, this feature is taught by Wallace (Col. 10, Ln. 40-50 and Col. 28, Ln. 22-34). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the teachings of Cunningham in view of Chorosinski in view of Tucker with the aforementioned teachings from Wallace with the motivation of having a means of providing a patient with a safe, automated, and low cost drug delivery system, as recited in Wallace (Col. 2, Ln. 8-15).

(B) As per claims 21 and 33, these claims are substantially similar to claim 8 and are therefore rejected on the same basis as claim 8, which is set forth above.

### ***Response to Arguments***

6. Applicant's arguments filed on December 22, 2009 have been fully considered but are moot in view of the new ground of rejection over the Tucker patent reference.

***Conclusion***

7. Applicant's amendment necessitated the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vivek Koppikar, whose telephone number is (571) 272-5109. The examiner can normally be reached from Monday to Friday between 8 AM and 4:30 PM.

If any attempt to reach the examiner by telephone is unsuccessful, the examiner's supervisor, Jerry O'Connor, can be reached at (571) 272-6787. The fax telephone numbers for this group are either (571) 273-8300 or (703) 872-9326 (for official communications including After Final communications labeled "Box AF").



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Another resource that is available to applicants is the Patent Application Information Retrieval (PAIR). Information regarding the status of an application can be obtained from the (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAX. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please feel free to contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sincerely,

/Vivek D Koppikar/

Primary Examiner, Art Unit 3686

1/15/2010